Plasma Standards Workshop

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Meeting Objectives and Overview

Obtain information to aid in the development of regulatory standards for “recovered plasma,” including labeling, freezing, storage and shipping conditions.

Review scientific data, regulatory requirements, and current industry practices regarding freezing, storage and shipping of plasma to ensure the safety, purity and potency of labile and non-labile plasma components, and potentially harmonize requirements with other regulatory bodies.

Ensure that regulatory decisions are based on science, need, and practicality.

Goals for Policymaking

- Identify the quality of plasma based on labeling to indicate conditions of freezing
- Remove barriers to conversion of plasma from transfusion use to use in fractionation
- Retain distinctions only as appropriate
  - Whole blood vs. apheresis
  - Product characterization based on intended use at the time of collection
  - Conditions of freezing
- Ensure that regulatory standards conform to the scientific state of the art

Perspective on the Workshop

- This workshop is only one venue for collecting information.
- Proprietary or confidential commercial information will be considered through discussions with the regulated industry.
- A docket will be provided for comments about this workshop and to provide a mechanism for sharing public information.
- Any policy proposals will be developed through a public process of notice and comment.

Meeting Agenda – Day 1

- Summary of 20 June 2003 Blood Products Advisory Committee recommendations for recovered plasma standards
  - The need to develop specifications for allowable storage conditions and dating periods
- Consumer perspective: need for high quality plasma products
- Manufacturing standards for plasma fractionation
  - Literature review of the effects of time to freezing, rate of freezing, and freezing and storage temperatures on integrity of plasma proteins

Meeting Agenda – Day 1

- Overview of current FDA regulations
  - Lack of regulations for recovered plasma
- Overview and rationale of international regulatory standards for plasma freezing, storage, and shipping
  - Standards of the Council of Europe and European Pharmacopoeia
  - Canadian standards
  - Australian standards

Meeting Agenda – Day 1

- Fractionation Practices
  - General overview
  - A fractionator's perspective on relation between source material and finished product
  - Review of current industry practices, including issues related to frozen storage, shipping practices, and impact of potential changes
- Current practices for freezing, storage, and shipping of plasma from the blood collection industry
  - Presentations from ARC, AABB, and ABC
- Panel Discussion

Meeting Agenda – Day 1

- Panel discussion on science, current practices and regulatory oversight of plasma preparation
  - What conditions of plasma collection, processing, shipping, and storage are necessary to ensure safety and efficacy of plasma derivatives?
    - Should the same standards apply to all plasma independent of the end products?
  - Should any restrictions be placed on further use of plasma based on the conditions of plasma collection, processing, shipping, and storage?

Meeting Agenda – Day 2

- Concepts for Regulation of Recovered Plasma
  - FDA
  - Blood industry
  - Plasma industry
- Panel Discussion

Meeting Agenda – Day 2

- Panel discussion of framework issues for possible licensing of recovered plasma
  - What should we call the various plasma products distributed for further manufacturing use?
  - How should they be labeled?
    - According to time and/or rate of freezing? (If so, what stratification is most appropriate?)
    - According to intended use?
  - What distinctions should be made from Source Plasma?